DRAFT

Oral Statement of Balchem Corporation
To the EPA Science Advisory Board for Presentation on the Teleconference for the Review of the Draft
IRIS Cancer Risk Assessment for Ethylene Oxide

December 8, 2006

Hello, my name is David Ludwig and I am The Vice President and General Manager and an Officer of Balchem Corporation. Balchem is one of the technical registrants for ETO. I appreciate the opportunity to address the SAB concerning their upcoming review of the draft IRIS cancer risk assessment for ETO. We have reviewed the draft cancer risk assessment. Our initial comments from that review were submitted to the docket today.

First, let me state that we fully support the position of the Ethylene Oxide/Ethylene Glycols Panel of the American Chemistry Council. We strongly encourage the SAB to review in detail the extensive comments submitted by the Panel on the draft cancer risk assessment prior to the January review meeting.

In addition to the charge questions posed to the SAB and the ACC Panel's questions we have some additional questions which I will get to in a minute but we also feel it is important today to take a minute to review the critical use of ETO as a sterilant to the medical field.

ETO provides unmatched public health benefits to society via its use by the medical community. In the United States alone ETO is used to successfully sterilize approximately 20 billion medical devices every year. The result of this risk assessment could limit or prevent ETO from being used as a sterilant for medical devices. If this happens:

- **Over 50 percent of all medical products provided in pre-sterilized packaged form would become unavailable; items such as syringes, IV tubing, surgical trays, catheters, orthopedic implants, vascular stents, and many other devices including simple items like band-aids.**
- **More than one third of all reusable devices currently sterilized by hospitals or their contract sterilization services would become unusable; such as surgical scalpels, endoscopes, laparoscopes, and many other reusable devices could no longer be safely sterilized or re-sterilized.**
- **Numerous essential or life-saving devices could no longer be sterilized; such as pacemakers, implantable defibrillators, and hundreds of other devices with electronic components.**
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Per AdvaMed's comments to the RED docket back in May of this year – I quote "In general, it is not feasible for medical device manufacturers to change to <u>any</u> other sterilization method within <u>any</u> realistic timeframe. For the vast majority of medical and laboratory products, ETO is the most efficient and effective means of sterilization available. In fact, for many products, ETO is the only acceptable method of sterilization."

Per the CDC - Healthcare Associated Infections (HAI) currently account for an estimated 2 million infections, 90,000 deaths, and $4.5 billion in excess health care costs annually." This is occurring even with ETO being used. Indeed, medical, hospital, and laboratory, settings rely on ETO to sterilize equipment to protect patients from the very real risks of infectious disease from bacteria and viruses. If ETO could no longer be used we could see a staggering increase in these infection figures.

If the medical device industry is forced to abandon ETO sterilization as its primary means of providing sterile medical devices, they will have to turn to alternatives that are either unreliable or certainly unproven. The result will most probably be a dramatic increase in the risk of infection through utilization of inadequately sterilized medical devices.

We urge SAB to recognize and correct the critical scientific deficiencies found throughout the Draft Risk Assessment and offer the following specific observations and recommendations:

- **Based on the extensive database of toxicological and epidemiological studies on EO, the cancer risk posed by EO is thousands of times less than portrayed in EPA's risk estimates.**

- **EPA's lymphatic cancer risk estimates for EO are based entirely on a single NIOSH retrospective study whose cohort was large, diverse and consisted of more women than men. While a slight increased risk of lymphatic cancer was observed in males, no increase was observed in females and all other cancer risks were found to be lower than expected. It must also be pointed out that the majority of this study's cohort were exposed to levels of ETO that were 50+ times higher than today's allowable exposure levels. These discrepancies raise fundamental questions about the EPA's ability for interpretation and reliance on this study population.**

- **The Agency's estimates of extra lifetime cancer incidence and mortality risk assume 85 years of exposure in contrast to the more-generally accepted and already-conservative assumption of 70 years of exposure. This unjustifiable increase of more than 20% adds further uncertainty and considerable increased conservatism into the excess lifetime cancer risk estimates for EO.**

- **EPA's risk estimates are implausible because they are significantly lower than natural background levels of EO in the atmosphere and the natural biological production of EO in the human body itself. If this risk estimate were accurate then the cancer rates and morality**

rates within the general public would already be thousand's of times higher than the current rates.

We urge SAB to revise this Draft Risk Assessment substantially by incorporating the foregoing comments along with those submitted by the American Chemistry Council. The SAB must take into account the seriousness of the potential outcome of this risk assessment – it could have a catastrophic effect on the healthcare system here in the United States and it will have potential worldwide implications as well.

Thank you for your attention.